510(k) Summary

ArthroCare® Corporation

Head and Neck Coblation® Wand

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
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Date Prepared:	August 9, 2013

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Device Name

Proprietary Name:	ArthroCare® Head and Neck Coblation® Wand
Common Name:	Head and Neck Coblation Wand
Classification Name:	Electrosurgical Device and Accessories
Device Class:	Class II
Product Code:	GEI
CFR Section:	21 CFR 878.4400

Predicate Device

Gyrus ACMI G3 Generator and Accessories-Dissector Plasma Knife	K080844 (August 13, 2009)

Description

The ArthroCare Head and Neck Coblation Wand is a bipolar, single use, electrosurgical device designed for use with the ArthroCare Coblator II System Controller for specific head and neck indications in otorhinolaryngology (ENT) procedures.

Intended Use/Indications For Use

The ArthroCare Head and Neck Coblation Wand is indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

- Cysts
- Tumors
- Head, neck, and oral surgery
- Neck mass

The ArthroCare Head and Neck Wand is designed to be used only with the ArthroCare ENT Coblator II (CII) Surgery System Controller and ArthroCare Flow Control Unit.

Performance Testing - Bench

Bench testing was performed to evaluate the performance of the Head and Neck Wand compared to the predicate Gyrus Dissector Plasma Knife. The Design Verification test results demonstrate that the Head and Neck Wand meets all design and performance specifications and performs comparably to the predicate device.

Performance Testing - Animal

A Pre-Clinical study was conducted in sheep to evaluate the tissue effects using the Head and Neck Wand compared to the predicate Gyrus Dissector Plasma Knife. Based on the test results, the proposed device is substantially equivalent to the predicate.

Performance Testing – Clinical

No clinical data are included in this submission.

Summary

All testing conducted demonstrates that the ArthroCare Head and Neck Coblation Wand performs as intended when used in accordance with its labeling. The ArthroCare Head and Neck Coblation Wand is substantially equivalent to the predicate Gyrus Dissector Plasma Knife in terms of design, principle of operation, and indications for use and raises no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 9, 2013

Ashley J. Dawson, Ph.D.
Manager, Regulatory Affairs
ArthroCare Corporation
7000 West William Cannon Drive
Austin, Texas 78735

Re: K131205
Trade/Device Name: ArthroCare® Head and Neck Coblation® Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 15, 2013
Received: July 16, 2013

Dear Dr. Dawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131205

Device Name: ArthroCare® Head and Neck Coblation® Wand

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-off)
Division of Surgical Devices
510(k) Number____K131205___